COPY FOR YOUR INFORMATION

J Davis 12-1-05 Laris #12

This report is required by law (7 USC 21 43) Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 2150

See reverse side for additional information

Interagency Report Control No 0580-DOA-AN

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

ANNUAL REPORT OF RESEARCH FACILITY
(TYPE OR PRINT)

1. REGISTRATION NO.
87-R-0001

FORM APPROVED
OMB NO. 0579-0036

2. HEADQUARTERS RESEARCH FACILITY (Name and Address, as registered with USDA Include Zip Code)

University of Utah

"A" 03/14/06

b2, b7f

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, teaching, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites)

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS FORM 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animals being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used	E. Number of animals upon which teaching experiments, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquilizing drugs would have adversely affected the procedures, results, or interpretation of the teaching, research, experiments, surgery, or tests. *(An explanation of the procedures producing pain or distress in those animals and the reasons such drugs were not used must be attached to this report)*	F. TOTAL NO OF ANIMALS (Cols. C + D + E)
4. Dogs	0	0	133	0	133
5. Cats	0	0	42	0	42
6. Guinea Pigs	0	33	100	297	430
7. Hamsters	0	0	16	0	16
8. Rabbits	0	218	592	0	810
9. Non-human Primates	0	0	9	0	9
10. Sheep	0	39	19	0	58
11. Pigs	0	15	100	0	115
Goats 12. Other Farm Animals	0	2	0	0	2
Bovine	0	3	31	0	34
Ferrets 13 Other Animals	0	64	0	0	64
Woodrats	33	55	0	0	~~88~~ 55
					Per telep. conv. 3-14

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during and following actual research, teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and approved by the Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

Rhonda Ahlquist 12-1-05

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)
I certify that the above is true, correct, and complete (7 U.S.C. Section 2143).

b6, b7c

DATE SIGNED
11/30/05

APHIS FORM 7023
(AUG 91)

Replaces VS ~~FORM~~ 18-23 (OCT 88) which is obsolete

DEC - 1 2005

Column E Explanation

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

1. Registration Number: 87-R-0001

2. Number 297 of animals used in this study.

3. Species (common name) Guinea Pigs of animals used in the study.

4. Explain the procedure producing pain and/or distress.

   The procedure performed is a skin sensitization test. The animals utilized in the test experience slight pain that is occasionally more than momentary. It consists of slight skin irritation.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see Item 6 below)

   Pain relievers in general, are anti-inflammatory and may interfere with optimization of the potential for detection of contact sensitization in this study design. Since inflammation is a component of the sensitization response being evaluated, introduction of agents that influence an inflammation response would most likely interfere with the evaluation of the potential of the test article to elicit a sensitization response.

6. What, if any, federal regulations require this procedure? Cite the agency, the code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):

   Agency ISO CFR 10993-1, parts 10 and 11

   (International Standards Organization)

February 6, 2006

In response to the follow-up question from Dr. Davis concerning Group E animals, we have performed an additional literature search using MEDLINE (January 31, 2006) with the key words "chlorpromazine", "Innovar-vet", "Opiates", "Opioids", "morphine", "ketamine", "fentanyl", "buprenorphine", "lidocaine", "ropivacaine", "bupivacaine", meperidine", "pentobarbital", "halothane", "naropin", "anesthesia", "analgesia", "anti-inflammatory response", and" immunomodualtion". The years covered by this search were 1965-present. Based upon this search, we were unable to find an analgesia method, potentially effective in guinea pigs, which does not effect the inflammatory reaction and/or the immune response which we are attempting to evaluate under this study protocol. In particular, Innovar-vet has been shown to induce pathologic changes at the site of drug deposition and thus altering the immune response. Opiates/Opioids have been proven to modulate the immune system. Specifically, both morphine and ketamine have been proven to affect the hemodynamic and inflammatory responses. Fentanyl and Buprenorphine exhibit immunosupression when used in acute or short-time administration and buprenorphine has been shown in various additional publications to alter the immune response. Finally, the local anesthetics of lidocaine, ropivacaine, and bupivacaine have been proven to alter the immune response by their affect on NK cells. In addition, we have spoken to several veterinarians and veterinary pathologists, as well as a researcher from the Anesthesiology Department in the School of Medicine of the University of Utah. None of these individuals are aware of any alternatives which would not, in some way, affect the inflammatory response and/or immune response that we induce in this study design.